

REMARKS/ARGUMENTS

Status of the Claims

Claims 14-23 are currently pending. In the present Response, claims 14, 15, 17, 18, 20-22 are amended; claim 23 is canceled; and claims 24-33 are added.

The claims have been amended to more particularly describe the claimed invention or correct typographical errors. Applicants submit that no new matter has been added by the instant claim amendments. For example, support for claim 14 can be found at least at page 5, lines 6-10 and lines 26-29, of the specification. Support for claim 15 can be found at least at page 11, line 34, to page 12, line 35. Support for claim 18 can be found at least at page 11, lines 21-22. Support for claim 20 can be found in the claim as originally filed and at least at page 18, lines 35-37. Support for amendments to claims 17, 21, and 22, can be found in the claims as originally filed. Support for new claim 33 can be found at least at page 3, lines 32-35. Support for new claims 24-32 directed to the use of an exendin in the methods of the invention can be found at least at page 14, lines 20-21; page 15, Table 1; page 16, lines 1-17; and the support for claims 14-22, and 33 set forth above.

Specification/Claim Objections

The Patent Office has raised informalities to the disclosure on page 2, of the Office Action. Applicants have amended the disclosure to obviate the objection. Applicants request reconsideration and withdrawal of the objection.

Issues under 35 U.S.C. §112, first paragraph

The Patent Office has rejected claim 15 under 35 U.S.C. §112, first paragraph, for allegedly containing subject matter which was not described in the specification in such a way as

to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Applicants respectfully disagree.

Applicants respectfully submit that there is sufficient description and guidance for one of ordinary skill in the art to make and use GLP-1 analogs. Initially, it should be remembered that the level of skill in the art, for example, protein synthesis and design, was very high at the time the instant application was filed. The knowledge to make and test compounds using routine molecular biological techniques was well-known in the field. For example, a search of the National Library of Medicine "pubmed" database for articles published before Oct. 9, 1998 with the terms "peptide" and "synthesis" returned 9,531 records. In addition to the knowledge and experience held by the skilled artisan, Applicants, on at least page 16, lines 18-35, and page 13, line 1 to page 14, line 2, of the specification, have provided further references and information to assist the skilled artisan in making compounds that can be used in the practice of the claimed invention. Applicants have also provided the skilled artisan with exemplary means for testing the activity of those compounds on page 17, lines 8-22.

Moreover, Applicants have described additional exemplary species of the genus of compounds (GLP-1 analogs), for example, Black Widow GLP-1 and Ser² GLP-1, and sources of additional information for analogs that can be used in the practice of the claimed invention on page 11, line 31, to page 14, line 2.

Finally, the Applicants remind the Patent Office that the Applicants discovered a novel and inventive method for preventing or ameliorating a decrease in a function of a tissue subjected to an ischemia-reperfusion event that includes administering a compound that binds to a GLP-1 receptor. Applicants' interest is in protecting this broad invention and not to the use of any particular GLP-1 analog described in the specification; therefore, Applicants submit that they should not be required to set forth every GLP-1 analog, some of which could not have been

known at the time of filing, to be granted the full protection of their invention to which they are entitled.

Applicants respectfully submit that the specification provides sufficient description and guidance for one of ordinary skill in the art to practice the claimed invention and request reconsideration and withdrawal of the instant rejection.

Issues under 35 U.S.C. §112, second paragraph

The Patent Office has rejected claims 14-23 under 35 U.S.C. §112, second paragraph, for allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Applicants respectfully submit that the claims as amended render this rejection moot.

The Patent Office alleges that in claim 14, the recitation of "improve the function of ischemic and reperfused tissue" is unclear. Applicants have amended claim 14 to clarify the scope of the pending claim. Thus, the dependent claims are similarly clarified.

The Patent Office alleges that in claim 15, the phrase "analog thereof" renders the limitation of claim 15 broader than that of claim 14 from which claim 15 depends. Applicants respectfully submit that the Applicants, being their own lexicographer, have defined GLP-1 to encompass both GLP-1 and its analogs, including mimetics (see at least page 11, line 31, to page 12, line 35). Applicants have therefore further defined the GLP-1 in claim 15.

The Patent Office alleges that claim 20 recites "continues thereof" and that this recitation makes it unclear as to whether or not every 4 hours, the administration is carried out and what is the end point for the continued administration. Applicants have amended claim 20 to clarify the scope of the claim.

The Patent Office alleges that claims 21 and 22 recite the limitations "the need for amelioration of tissue damage" and "the medical procedure," respectively, which finds insufficient basis in claim 14 from which they depend. Applicants have amended claims 21 and 22 to obviate this rejection.

Applicants respectfully submit that the above amendments to the claims were made to clarify the scope of the claims and do not narrow the scope of the claims as originally presented. Applicants respectfully request reconsideration and withdrawal of the rejection based upon 35 U.S.C. §112, second paragraph, to the claims as amended.

Issues under 35 U.S.C. §102

The Patent Office has rejected claim 23 for allegedly being anticipated by U.S. Patent No. 6,410,513 to Galloway *et al.* Applicants have cancelled claim 23, thereby rendering this rejection moot.

Issues regarding Obviousness Type Double Patenting

The Patent Office has rejected claims 14-20 under the judicially created doctrine of obviousness-type double patenting of claims 1-8 and 10 of U.S. Patent No. 6,429,197. The Patent Office has also rejected claims 14-20 under the judicially created doctrine of obviousness-type double patenting of claims 1-5 and 8-13 of U.S. Patent No. 6,284,725. Applicants have filed the appropriate terminal disclaimer to overcome this rejection. Accordingly, Applicants respectfully request reconsideration and withdrawal of the instant rejection.

Applicants respectfully request consideration of the references in the instant Information Disclosure Statement.

CONCLUSION

Applicants respectfully submit that the claims are now in condition for allowance and request that a timely Notice of Allowance be issued in this case. The Examiner is encouraged to call the undersigned attorney to discuss any issues related to the prosecution of the instant application.

Applicants believe that no additional fee is necessitated by the present paper. However, in the event any fees are due or any amount is to be credited, Applicants authorize the Commissioner of Patents to debit or credit Deposit Account No. 010535.

Respectfully submitted,



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Attachments: Terminal Disclaimer, Information Disclosure Statement and related papers.